News from Ed Markey

United States Congress **Massachusetts Seventh District**
FOR IMMEDIATE RELEASE **CONTACT: Tara McGuinness or**
September 14, 2005 **Kate Reinhalter**
(202) 225-2836

REP. MARKEY INVESTIGATES FDA FAILURE TO INFORM THE PUBLIC OF HEART DEVICE RISK

Markey Asks: Is this FDA "Incompetence" or is the FDA Protecting Drug Companies?

Washington, D.C. – Rep. Edward J. Markey (D-MA), a Senior Member of the Energy and Commerce Committee, today sent a letter to the Food and Drug Administration (FDA) asking questions about the FDA's slow response to Guidant's report that their widely used defibrillators were short-circuiting at the rate of about one a month. Despite receiving this report, the FDA did not inform the public of the health risk for four months. The FDA reported that they were unable to release the failure rate immediately because of confidentiality agreements with the company.

Rep. Markey said, "The public deserves to know whether is a case of FDA incompetence and lack of diligence, or whether the FDA made a decision to protect the company's confidentiality over the public health. Either way, we have a serious problem on our hands. The FDA has a duty to protect the public health and communicate these serious safety issues to public immediately."

The letter addressed to the FDA Commissioner requests responses to the following questions:

1. When did the FDA review Guidant's annual report?
2. When did the FDA initiate the investigation of the failure rate of the Ventak Prizm 2 DR?
3. In the case of the Ventak Prizm 2 DR, how long did it take the FDA to determine what data could be released and what should be treated as confidential?
4. What percentage of the annual reports are reviewed within 30 days following submission? In 60 days? In 90 days? In more than 90 days?
5. Prior to conducting a full review of the annual report, does the FDA have a process to identify which reports contain information that require immediate attention?
6. Does the FDA have a system in place to routinely inform the public of the failure rate of medical devices, the number of device failures and the reasons for the failures?
7. Does the FDA have the resources it needs to review these filings and promptly inform the public if the filings contain evidence of a significant safety issue?
8. Does the FDA believe that it is ever appropriate to release confidential or proprietary information? If so, has the FDA ever released confidential or proprietary information? If

so, please list the times that the FDA has released such information and explain the circumstances of the release.

9. Would the FDA have alerted the public of the safety issues with the Ventak Prizm 2 DR even if Guidant had not?
10. What aspect of the failure rate of a device is proprietary and needs to be kept confidential?
11. How does the FDA believe it is reasonable to wait before informing the public of a significant safety concern? In the case of a life-threatening safety issue?
12. Is the FDA developing a system to that would separate the failure rate information from the other confidential and proprietary information in the annual report and allow the FDA to immediately release the failure rate information and along with any appropriate safety warnings?

For more information on Rep. Markey's work on FDA reform and copies of the letters sent to the FDA, please go to http://www.house.gov/markey/healthgen.htm

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